

with the following prescribed conditions:

(a) The additive is the chemical green ferric ammonium citrate.

(b) The additive is used or intended for use as an anticaking agent in salt for animal consumption so that the level of iron ammonium citrate does not exceed 25 parts per million (0.0025 percent) in the finished salt.

(c) To assure safe use of the additive the label or labeling of the additive shall bear, in addition to the other information required by the Act:

(1) The name of the additive.

(2) Adequate directions to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

§ 573.580 Iron-choline citrate complex.

Iron-choline citrate complex made by reacting approximately equimolecular quantities of ferric hydroxide, choline, and citric acid may be safely used as a source of iron in animal feed.

§ 573.600 Lignin sulfonates.

Lignin sulfonates may be safely used in animal feeds in accordance with the following prescribed conditions:

(a) For the purpose of this section, the food additive is either one, or a combination of, the ammonium, calcium, magnesium, or sodium salts of the extract of spent sulfite liquor derived from the sulfite digestion of wood or of abaca (*Musa textilis*) or of sisal (*Agave sisalana*) in either a liquid form (moisture not to exceed 50 percent by weight) or dry form (moisture not to exceed 6 percent by weight).

(b) It is used or intended for use in an amount calculated on a dry weight basis, as follows:

(1) As a pelleting aid in the liquid or dry form in an amount not to exceed 4 percent of the finished pellets.

(2) As a binding aid in the liquid form in the flaking of feed grains in an amount not to exceed 4 percent of the flaked grain.

(3) As a surfactant in molasses used in feeds, as liquid lignin sulfonate, in an amount not to exceed 11 percent of the molasses.

(4) As a source of metabolizable energy, in the liquid or dry form, in an

amount not to exceed 4 percent of the finished feed.

§ 573.620 Menadione dimethylpyrimidinol bisulfite.

The food additive, menadione dimethylpyrimidinol bisulfite, may be safely used in accordance with the following conditions:

(a) The additive is the 2-hydroxy-4,6-dimethylpyrimidinol salt of menadione ($C_{17}H_{18}O_6N_2S$).

(b) The additive is used or intended for use as a nutritional supplement for the prevention of vitamin K deficiency as follows:

(1) In chicken and turkey feed at a level not to exceed 2 grams per ton of complete feed.

(2) In the feed of growing and finishing swine at a level not to exceed 10 grams per ton of feed.

(c) To assure safe use, the label and labeling of the additive shall bear adequate directions for use.

§ 573.625 Menadione nicotinamide bisulfite.

The food additive may be safely used as follows:

(a) *Product.* The additive is 1,2,3,4-tetrahydro-2-methyl-1,4-dioxo-2-naphthalene sulfonic acid with 3-pyridine carboxylic acid amine (CAS No. 73581-79-0).

(b) *Conditions of use.* As a nutritional supplement in chicken and turkey feeds for both the prevention of vitamin K deficiency and as a source of supplemental niacin.

(c) *Limitations.* Not to exceed 2 grams per ton of complete feed. To assure safe use, the label and labeling shall bear adequate directions for use.

[61 FR 5, Jan. 2, 1996]

§ 573.640 Methyl esters of higher fatty acids.

The food additive methyl esters of higher fatty acids may be safely used in animal feeds in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reaction of methyl alcohol with feed-grade fats or oils and consists of not less than 70 percent methyl esters of the following straight-chain monocarboxylic acids: Docosahexanoic acid, eicosapentanoic acid, linoleic

acid, myristic acid, oleic acid, palmitic acid, palmitoleic acid, and stearic acid, and lesser amounts of the associated acid esters.

(b) The food additive meets the following specifications:

(1) Free methyl alcohol not to exceed 150 parts per million.

(2) Unsaponifiable matter not to exceed 2 percent.

(3) It is free of chick-edema factor or other factors toxic to chicks, as evidenced during the bioassay method for determining the chick-edema factor as prescribed in paragraph (b)(4)(ii) of this section.

(4) For the purposes of this section:

(i) Unsaponifiable matter shall be determined by the method described in Section 28.081, "Unsaponifiable Residue (20)—Official Final Action" of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed., 1980, p. 451, which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201-3301, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(ii) The chick-edema factor bioassay method described under "26. Oils, Fats, and Waxes" in the *Journal of the Association of Official Agricultural Chemists*, Vol. 44, Page 146 (1961), or the method described under "Chick-Edema Factor—Bioassay Method (34)—Official Final Action" in §§ 28.113–28.117, "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed., 1975, pp. 509–511, which is incorporated by reference, shall be employed. (Copies of the methods are available from the Association of Official Analytical Chemists, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201-3301, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.) The presence of chick-edema factor shall be determined by a comparison between the mean log of the pericardial fluid volumes of a test group and of a concurrent negative control group. The significance of the difference in pericardial fluid volumes between the test group and the nega-

tive control group is determined by calculating a "t" value according to the formula:

$$t = \frac{\bar{x}_t - \bar{x}_c}{\sqrt{(s_t^2/n_t) + (s_c^2/n_c)}}$$

where:

\bar{x}_t and \bar{x}_c are the means of the logs of the pericardial fluid volumes of the test and control groups, respectively;

n_t and n_c are the number of chicks in the respective groups;

s_t^2 and s_c^2 are the variances of the test and control groups, respectively.

The variances are calculated as follows:

$$s^2 = \frac{n(\sum x^2) - (\sum x)^2}{n(n-1)}$$

where:

$\sum x$ is the sum of the logs of the pericardial fluid volumes;

$\sum x^2$ is the sum of the squares of the logs of the pericardial fluid volumes for either the test t or control c group data.

The test sample is judged to contain chick-edema factor if the calculated "t" exceeds +1.3 and the mean log of the pericardial fluid volume obtained from the negative control group multiplied by 100 is less than 1.1461.

(iii) "Other factors toxic to chicks" referred to in paragraph (b)(3) of this section shall be determined during the course of the bioassay test described in paragraph (b)(4)(ii) of this section, on the basis of chick deaths or other abnormalities not attributable to chick-edema factor or to the experimental conditions of the test.

(c) It is used or intended for use as a supplementary source of fat for animal feed.

(d) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label and labeling of the additive, and any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall bear:

(i) The name of the additive.

(ii) The designation "feed grade" in juxtaposition with the name and equally as prominent.

(2) The label or labeling of the additive and any feed additive supplement, feed additive concentrate, feed additive

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premix, or complete feed prepared therefrom shall bear adequate directions for use.

[41 FR 38652, Sept. 10, 1976, as amended at 47 FR 9397, Mar. 5, 1982; 54 FR 18281, Apr. 28, 1989]

§ 573.660 Methyl glucoside-coconut oil ester.

Methyl glucoside-coconut oil ester may be safely used in accordance with the following conditions:

(a) The additive meets the specifications prescribed in § 172.816 of this chapter.

(b) It is used as a surfactant in molasses intended for use in animal feed at a level not to exceed 320 parts per million.

§ 573.680 Mineral oil.

Mineral oil may be safely used in animal feed, subject to the provisions of this section.

(a) Mineral oil, for the purpose of this section, is that complying with the definition and specifications contained in § 172.878 (a) and (b) or in § 178.3620(b)(1) (i) and (ii) of this chapter.

(b) It is used in animal feeds for the following purposes:

(1) To reduce dustiness of feeds or mineral supplements.

(2) To serve as a lubricant in the preparation of pellets, cubes, or blocks and to improve resistance to moisture of such pellets, cubes, or blocks.

(3) To prevent the segregation of trace minerals in mineralized salt.

(4) To serve as a diluent carrier in the manufacture of feed grade biuret in accordance with good manufacturing practice.

(5) For the removal of water from substances intended as ingredients of animal feed.

(c) The quantity of mineral oil used in animal feed shall not exceed 3.0 percent in mineral supplements, nor shall it exceed 0.06 percent of the total ration when present in feed or feed concentrates.

[41 FR 38652, Sept. 10, 1976, as amended at 47 FR 41106, Sept. 17, 1982]

§ 573.700 Sodium nitrite.

Sodium nitrite may be safely used in canned pet food containing meat and

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fish in accordance with the following prescribed conditions:

(a) It is used or intended for use alone as a preservative and color fixative in canned pet food containing fish, meat, and fish and meat byproducts so that the level of sodium nitrite does not exceed 20 parts per million.

(b) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label of the additive shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive in any mixture.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (a) of this section.

§ 573.720 Petrolatum.

Petrolatum may be safely used in or on animal feed, subject to the following prescribed conditions:

(a) Petrolatum complies with the specifications set forth in the U.S. Pharmacopeia XVI for white petrolatum or in The National Formulary XII for yellow petrolatum.

(b) Petrolatum meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in § 172.886(b) of this chapter.

Ultraviolet absorbance per centimeter path length:

| Millimicrons | Maximum |
|------------------|---------|
| 280 to 289 | 0.25 |
| 290 to 299 | .20 |
| 300 to 359 | .14 |
| 360 to 400 | .04 |

(c) It is used in animal feed for the following purposes:

(1) To reduce dustiness of feeds or mineral supplements.

(2) To serve as a lubricant in the preparation of pellets, cubes, or blocks, and to improve resistance to moisture of such pellets, cubes, or blocks.

(d) The quantity of petrolatum present in animal feeds from the uses specified in paragraph (c) of this section shall not exceed 3 percent in mineral supplements nor shall it exceed 0.06 percent of the total ration when present in feed or feed concentrates.